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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/824,043      | 04/13/2004  | Thomas J. Maginot    | 22220-09031         | 6032             |

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| EXAMINER |
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PREBILIC, PAUL B

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| ART UNIT | PAPER NUMBER |
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3738

DATE MAILED: 01/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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|------------------------------|--------------------------------------|---|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/824,043 | <b>Applicant(s)</b><br>MAGINOT, THOMAS J. |  |
|                              | <b>Examiner</b><br>Paul B. Prebilic  | <b>Art Unit</b><br>3738                   |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**P r i o d f r Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 October 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-12 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1 and 4-6 is/are allowed.
- 6) ☒ Claim(s) 2, 3 and 7-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>10/7/04</u> . | 6) <input type="checkbox"/> Other: _____  |

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 3, and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 2 and 3, on lines 8-9 of claim 2, "the sectional dimension" lacks antecedent basis and renders the claim scope indefinite because there are an infinite number of sections one could take of an object along a variety of axes.

Regarding claim 12, on line 3, "another end" is unclear there should be only two ends of the graft as disclosed. For this reason, it is unclear whether the previous "another end" is being modified or whether a new "another end" is being introduced. The Examiner suggests changing this terminology to ---said another end--- or ---the another end--- in order to overcome this rejection.

***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 11 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 2 of U.S. Patent No. 6,401,721. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims are so similar that they read on each other. In particular, claim 11 is different than claim 2 in that it does not require the medical instrument. However, claim 11 requires an additional anastomosis formation that claim 2 does not. However, the use of a medical instrument with the claim 11 device would have been clearly obvious because it would be difficult if not impossible to insert the graft by hand. Furthermore, the additional anastomosis step of claim 11 is obvious in view of claim 2 because claim 2 is drawn to a bypass method for directing blood flow from one blood vessel or location to another blood vessel or location. In other words, the second anastomosis is implied by the preamble of claim 2. For these reason, the claims are considered to be obvious in view of each other.

### ***Claim Rejections Based Upon Prior Art***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 7-10 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Kreamer (US 4,577,631) alone. Kreamer anticipates the claim language where the incision into the body is considered inherent because a hole or opening into the femoral artery as shown by Kreamer is not naturally present; see Figures 8-10 and column 5, line 55 to column 7, line 2. The claimed step of anastomosis is considered met by Kreamer since the graft is adhesively attached to the inside of the vessel.

Alternatively, one may not consider the Kreamer adhesive attachment to be an anastomotic procedure as claimed. However, the Examiner asserts that it would have been at least obvious to form an end-to-end anastomosis since an anastomosis is merely a manner of connecting lumens together.

Claims 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Donaldson (US 2,935,068) in view of Sparks (US 3,710,777). Donaldson teaches that it was known to use bypass grafts to attach a number of different arteries; see the figures, especially Figures 3, where an aortic and femoral artery is attached) as well as column 2, lines 11-16 and column 5, line 67 to column 6, line 16. However, Donaldson fails to teach inserting the graft through the incision upwardsly along the aorta as claimed. Sparks teaches using a tunneling tube to insert a graft through tissue and form side-to-end anastomosis along an artery; see Figure 19 and column 3, line 2 to column 5, line 60. Therefore, it would have been prima facie obvious to one of ordinary skill to

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attach one end of the Donaldson graft to an aorta (i.e. an artery) and another blood vessel such as a femoral artery as taught by Donaldson by using the tunneling tube technique disclosed by Sparks. One would be motivated to use the Sparks technique in order to avoid making a long incision (more invasive procedure), and for the same reasons that Spark uses the same.

### ***Allowable Subject Matter***

Claims 1 and 4-6 are allowed over the prior art of record.

Claim 3 is would be objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The claim would have to be rewritten to not include the indefinite language of present claim 2.

### ***Conclusion***

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action if the application is not stored in image format (i.e. the IFW system).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Paul B. Prebilic whose telephone number is (571) 272-4758. He can normally be reached on 6:30-5:00 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, McDermott Corrine can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read "Paul Prebilic", with a stylized flourish at the end.

Paul Prebilic  
Primary Examiner  
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